## Oral Comments Provided for Consideration on the second external review draft of the Integrated Science Assessment for Ozone and Related Photochemical Oxidants

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I am professor Milan Hazucha at the Department of Medicine, School of Medicine and the Center for Environmental Medicine, Asthma and Lung Biology, University of North Carolina, Chapel Hill. My research interests include controlled human exposure studies of air pollutants, particularly ozone, PM, SO<sub>x</sub>, NO<sub>x</sub> specifically NO, and CO.

These comments reflect some of the main points Dr. Allen Lefohn and I submitted in written form to the Docket. The views expressed herein are exclusively the authors' and do not represent any official policy of the institutions in which we are employed or any other organization.

- 1. The use of Filtered Air (FA) may not be an appropriate control exposure because the 0 ppb O<sub>3</sub> FA generated in the laboratory does not exist under ambient or indoor air conditions. We believe that it is important for EPA to discuss in the ISA whether statistically significant effects observed at concentrations below the current standard, when compared to a FA control, retain the same statistical significance if the results were compared to Policy Relevant Background (PRB) O<sub>3</sub> concentrations. The latest research results published in the literature indicate that hourly average concentrations ≥ 50 ppb frequently occur under PRB conditions at some sites in the US. Thus, comparing ozone responses to an unrealistic FA control exposure is misleading.
- 2. Comparing the average changes across corresponding time intervals using either the absolute or relative difference between the O<sub>3</sub> and FA responses and expressing them as "ozone-induced" is misleading. The FA responses in such adjustments may substantially

- "artificially" enhance or diminish the magnitude of the O<sub>3</sub> response. This presents potentially misrepresentation of the results. In order to correctly interpret what the "ozone-induced" effects are, it is necessary to discuss pre- to post-exposure differences as well.
- 3. Temporal pattern of changes provide important information on intra-individual variability of response. With considerable between and within exposure variability of individual's FEV<sub>1</sub>, the utility of using only the end-exposure FEV<sub>1</sub> value for health assessment is inadequate.
- 4. **It is unsettling that the Agency** has modified its policy on the acceptance of research data for the support of the national standard by accepting non peer-reviewed material as well. The acceptance of material which is not available for a peer-reviewed scrutiny casts doubts on the quality of data on which the EPA recommendations and conclusions are based.
- 5. We suggest that the EPA write a section in the ISA that discusses the similarities between human health and vegetation research results. There are number of important similarities between human health and vegetation research findings in both the mechanisms as well as the pattern of response that should not be ignored. For example, (1) ozone effects are cumulative and (2) peak concentrations appear to be more important in eliciting the effects than the averaging of concentrations would suggest (Hazucha and Lefohn, 2007; Lefohn et al. 2010). These findings noted by vegetation researchers formed a basis for recommending a cumulative exposure index that provides greater weight to the higher ozone concentrations versus the mid-level values. Controlled human laboratory studies have shown that there is a disproportionately greater pulmonary function response from higher hourly average O<sub>3</sub> concentrations than from lower hourly average values. Thus, the efficacy of the current 8-h O<sub>3</sub> standard is reduced by not reflecting adequately the dose-response relationship which is not monotonic over an 8-h period.
- 6. **In September of 2011 president Obama ordered EPA administrator** to withdraw the proposed revision to the ambient air quality standard for O<sub>3</sub>. This provides a unique opportunity to identify alternative forms for the human health standard. The alternative approach, such a cumulative exposure index, may be more appropriate to protect human health than the current form of the standard.

## References

- Hazucha, M., Lefohn, A.S., 2007. Nonlinearity in Human Health Response to Ozone: Experimental Laboratory Considerations Atmospheric Environment. 41: 4559-4570.
- Lefohn, A.S., Hazucha, M.J., Shadwick, D., Adams, W.C., 2010. An Alternative Form and Level of the Human Health Ozone Standard. Inhalation Toxicology. 22:999–1011.